ASSESSMENT OF XEROPHTHALMIA AND THE MASS VITAMIN A PROPHYLAXIS PROGRAM IN EL SALVADOR

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PROJECT REPORT

ASSESSMENT OF XEROPHTHALMIA

AND

THE MASS VITAMIN A PROPHYLAXIS PROGRAM IN EL SALVADOR

September 1973 - December 1974

By

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INTRODUCTION

Hypovitaminosis A is thought to be the most important cause of childhood blindness in many underdeveloped countries[1-5]. Although firm statistics are lacking, the problem is felt to be of such urgency that an Expert Group of the Pan American Health Organization has officially recommended vitamin A supplementation of the preschool-age population, either by periodic mass distribution of vitamin A capsules or vitamin A fortification of staple food products[6].

Surveys by the Institute of Nutrition of Central America and Panama (INCAP) identified El Salvador as having the highest prevalence of hypovitaminosis A in Central America[7], and a hospital-based study demonstrated that 20% of children suffering from marasmus, and 12% suffering from Kwashiorkor had concommitant clinical (corneal) evidence of severe vitamin A deficiency[8,9]. Biannual mass distribution of vitamin A capsules was begun in April of 1973 as part of a country-wide vaccination campaign. Similar pilot or nationwide programs are currently underway in India, Indonesia, and the Philippines, and the World Health Organization and UNICEF are conducting one in Bangladesh[5].

The basic assumption in all these programs is that periodic mass distribution of vitamin A will effectively reduce the incidence of keratomalacia and other vitamin A related forms of corneal destruction and resultant blindness. This has never been demonstrated. Evaluation of the effectiveness of the vitamin A distribution program in El Salvador in reducing the incidence and prevalence of vitamin A related corneal destruction among preschool-age children provided an opportunity for testing this assumption.

BACKGROUND[10]

El Salvador is the smallest and most densely populated country in Central America, with

over 400 people per square mile, and an estimated 1970 population of 3.4 million. Infant mortality, 63.4 per 1,000 live births, and annual growth rate, 3.4 percent, are high.

Forty percent of the population is considered urban, although the society is basically rural. The poorest socio-economic groups are rural laborers. Over 100,000 small farmers live on less than one hectare (2.47 acres) of land. According to government statistics, piped water supplies are accessible to only 23 percent of rural families, and less than one percent have sewage disposal facilities. Seventy-five percent of the rural homes are of wattle or adobe construction, and few, if any, have electricity. Not surprisingly, gastroenteritis is the leading cause of morbidity and mortality, especially among the pediatric age groups.

The small size of El Salvador (roughly 60x160 miles), accessability of even the remotest areas, and apparent high prevalence of clinically significant hypovitaminosis A, made it an ideal country in which to carry out the proposed study.

METHODS

The study consisted of two major components: a nationwide prevalence survey of vitamin A related ocular pathology among preschool-age children, and a retrospective chart review of hospitalized keratomalacia cases. In addition, inquiry was made of the daytime visual status of each family member included in a country-wide questionnaire survey conducted by the Asociacion Demografica Salvadoreña.

All data was recorded on precoded forms, transfered to 80 column IBM cards, and analyzed by sorter and computer.

Vitamin A was distributed by the government of El Salvador as part of their well-publicized mass vaccination campaigns in April and May, and again in November and December of 1973. Every child between the ages of 1 and 5 present at the distribution center had the contents of a capsule

over 400 people per square mile, and an extraordinarily high [illegible]

mortality, [illegible] per 1,000 live births [illegible]

Forty percent of [illegible]

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[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

of 200,000 IU vitamin A and 40 IU of vitamin E squeezed into his mouth. Vigorous attempts were made to track down absent children (Appendix #1). Principal members of the present study were in no way involved in either the design or execution of the distribution program.

STUDY I. COUNTRY-WIDE PREVALENCE SURVEY

METHODS AND MATERIALS

To gauge the magnitude of the vitamin A problem and establish a baseline for assessing the effectiveness of the mass distribution program, a country-wide prevalence survey of 10,000 children, ages one through six, was conducted during October-December of 1973. Fifty-nine sample sites were selected by a multistage stratified technique with representation proportional to size (Appendix #2). The slum areas of the three major cities, San Salvador, Santa Ana, and San Miguel, comprised the "urban" sample. A review of Bloom Hospital's monthly reports supported the clinical impression that vitamin A deficiency was not a problem among the wealthier urban classes. Recently prepared maps which listed every house in each of the sample sites were provided by Asociacion Demografica Salvadoreña.

The field team was composed of an ophthalmologist, three two-nurse teams, a nurse supervisor, and three drivers with vehicles. Each nurse team was assigned a specific sector of that day's sample site. The nurses entered each house in their sector, compiled identifying (name, age, sex) and socio-economic (number of people per room) data on every eligible child in the household, and assembled all available children at a central point for the ophthalmologist. He examined the anterior segment of every child's eyes with a handlight, noted obvious abnormalities, and estimated the potential visual acuity as better or worse than 20/200. Special attention was paid to those lesions potentially related to active xerophthalmia (conjunctival

wrinkling and xerosis, bitot spots, corneal xerosis, and keratomalacia) and its healed sequelae (nebulae, leukomata, staphylomata, and phthisis bulbi).

With historical data provided by an older family member, usually the mother, the ophthalmologist attempted to assign etiologies to all old, healed corneal abnormalities. The major categories included infection (gross purulence), measles (characteristic rash), trauma (clear-cut history of injury at the time of onset of the corneal damage), congenital (noted at or shortly after birth in an otherwise white and quiet eye), hypovitaminosis A (none of the above in an otherwise white and quiet eye - children invariably severely malnourished).

One team measured the height and weight (Salter Hanging Scale) of all the children they examined (one-third of the entire sample), as well as all children with active signs of vitamin A deficiency and a matched control (the next normal child of the same age and sex). An attempt was made to get 5-8 cc of venous blood from each of these same abnormals and controls. The blood was immediately placed in a light-tight container with ice, and spun and separated at the end of the day. All vitamin A determinations were performed by the Division of Physiological Chemistry, INCAP.

The nurse-supervisor reviewed 20-40% of all forms in the field, checking the responses with the families actually studied.

RESULTS

After four weeks of training and standardization, two of them in the field, the study got underway on October 15 and was completed by late December, 1973.

Sample:

A total of 51 sample sites, out of the initial 59, were visited. One was omitted because it lay in a militarily restricted zone. The rest, the last sites to be visited, had already received

the second vitamin A distribution by mistake. Anticipating this possibility, these sites were randomly scattered across the country to prevent geographic bias. One of the 51 sites represented substitution of an alternative for one which was totally inaccessible.

SAMPLE SITES IN EL SALVADOR

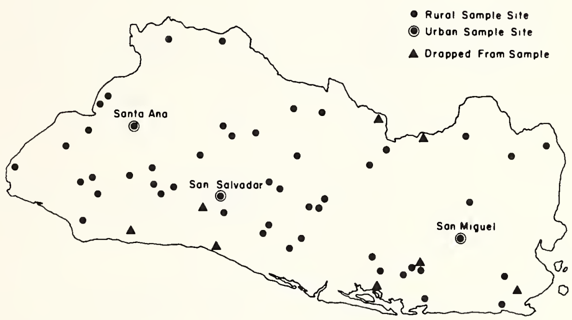

Fig. 1

A total of 9,014 houses were visited. Nine hundred and fifty-six of these houses were empty, 1,550 did not contain children under age 7, and an additional 48 were not examined for unknown reasons. Of 6,460 houses in which eligible children were present, 788 or 12% did not contribute to the sample. Two hundred and ninety-eight of these families refused to cooperate, and 490 did not have any adults present. Thus, a total of 5,672 families were studied.

TABLE I

HOUSES VISITED IN THE SAMPLE SITES

A. Houses with Eligible Children		
	1. contributed children	5,672
	2. refused	298
	3. no adults present	490
	Total	6,460
B. Houses without Eligible Children		
	1. empty	956
	2. no children under 7 years	1,550
	3. other	48
	Total	2,554
Total houses visited		9,014

Sample families contained 9,743 eligible children. Two hundred and thirty-five or 2.4% were listed but unavailable for examination. This represented 3.8% of urban and 1.7% of rural eligible children. There was little variation with age.

Age:

Table 2 shows the age distribution of the 9,508 children examined. These represent 1.2% of the estimated number of 1-6 year-olds in the entire country[11]. Again, there is little variation with age, indicating lack of any significant sample bias. As planned, the size of the rural sample is approximately twice the urban.

TABLE 2

CHILDREN EXAMINED

Geographic Zone	Age in Years Completed 1	2	3	4	5	6	Unknown	Total
Urban	518	532	500	505	529	517	25	3,126
Rural	1,078	1,057	1,118	982	1,005	1,072	70	6,382
Total	1,596	1,589	1,618	1,487	1,534	1,589	95	9,508

Sex:

Through an oversight, the final field form omitted designation of sex. Instead, a systematic sample of forms of 100 families from the three urban sites, and 200 families from fifteen of the 48 rural sites were reviewed, and each child's sex was determined from his or her name. Overall, the number of males and females in this subsample was exactly equal (307:307). There was an insignificant differential between rural (223 male to 220 female) and urban (84 male to 87 female) samples.

Active Signs of Vitamin A Deficiency:

Only five children in the entire sample had bitot spots, for a prevalence of 5.3 per 10,000

(Table 3). None of these children were under the age of three, and three were five years or older (Table 4). Four of these five children were from the rural sample, a representation twice that of the sample as a whole. The single urban child was from Santa Ana.

TABLE 3

OCULAR SIGNS OF VITAMIN A DEFICIENCY AMONG 1-6 YEAR OLDS

	Positives/Sample	Prevalence (per 10,000)	Prevalence (percent)
Bitot Spots	5/9508	5.3	.053
Healed Corneal Lesions	3/9508	3.2	.032

Wrinkling was not considered a useful sign because of the lack of sharp definition, especially in the urban area where it was modified. In no instance did it accompany other evidence of vitamin A deficiency or severe malnutrition. Four-tenths of one percent of the rural sample showed unusual degrees of wrinkling. None were under the age of four. At age four there was a sharp rise in prevalence to 1.2 percent, which persisted among older children.

No cases of active corneal involvement (xerosis or keratomalacia) were uncovered.

Healed Corneal Evidence of Presumed Vitamin A Deficiency:

Only three children in the entire sample had corneal damage thought to be secondary to vitamin A deficiency, for a prevalence of 3.2 per 10,000 children (Table 3). The three children were two, four, and six years old (Table 4) suggesting a cohort effect with the damage having occurred early in life, around age two. The six-year-old incurred his corneal damage at the age of two, supporting the above conclusion. Age of onset in the four-year-old was unknown.

(Table 3). None of these children [illegible] under the age of three [illegible]

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[illegible]

TABLE 4

AGE DISTRIBUTION OF CHILDREN WITH OCULAR SIGNS OF VITAMIN A DEFICIENCY

Age (Years Completed)	Number of Positives	
	Bitot Spots	Corneal Disease
1	--	--
2	--	1
3	2	--
4	--	1
5	1	--
6	2	1
Total	5	3

Two of these children had a unilateral adherent leukoma, and one a staphyloma and adherent leukoma in one eye, and an adherent leukoma and phthisis bulbi in the other eye. Each child was felt to have a visual acuity less than 20/200 in the involved eye(s). One of the children (the two-year-old) had been seen and treated for keratomalacia at the Bloom Hospital.

The oldest of the three was a male, and the other two female. All three were from the rural sample, but the numbers are too small for statistical significance.

Extent of the Vitamin A Problem:

Table 5 depicts the estimated ocular impact of hypovitaminosis A in El Salvador. The

prevalence of corneal disease was 32 per 100,000. There are approximately 43 new surviving cases of corneal involvement and 15 new blindnesses per year. While the number of positive cases is small (3), the confidence limits provide a relatively accurate estimate (with 95% certainty) of the true magnitude of the problem.

TABLE 5

ESTIMATED IMPACT OF VITAMIN A RELATED CORNEAL DISEASE

	Mean	Confidence Limits (± 2 Standard Deviations)
Prevalence of Corneal Disease	32/100,000	0-68/100,000
New Surviving Cases per year	43	0-90
New Blindnesses per year	15	0-45

Prevalence of Corneal Opacities:

A total of 36 children had corneal opacities detectable with a handlight (Table 6). The majority, 56%, were secondary to trauma. Infection accounted for 17%, measles 11%, and presumed hypovitaminosis A 8%. There was a strong association between both trauma and measles induced lesions and urban dwelling (Table 7). Children living in cities were at 19 times greater risk of acquiring a traumatic, and six times greater risk a measles associated corneal lesion than their rural counterparts. These differences were statistically significant.

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TABLE 6

CAUSES OF CORNEAL OPACITIES AMONG 1-6 YEAR OLDS

	Cases	Percent of Total
Trauma	20	56
Infection	6	17
Measles	4	11
Hypovitaminosos A	3	8
Congenital	1	3
Unknown	2	6
	36	101

TABLE 7

RELATIVE RISKS OF CORNEAL OPACITIES - URBAN : RURAL

	Cases U : R	Relative Risk U : R
Trauma	18 : 2	19 : 1**
Measles	3 : 1	6 : 1**
Infection	2 : 4	1 : 1
Hypovitaminosis A	0 : 3	0 : 1.5
Overall	27 : 9	6 : 1**

**P < .05

As would be expected, the prevalence of traumatic lesions increased with age. Among 4-6 year-olds it was more than twice that of 1-3 year-olds (282:125 per 100,000). Males accounted for two-thirds of the 18 cases for which the sex was noted. The prevalence of traumatic corneal lesions in the urban sample was 576 per 100,000, vs. only 31 per 100,000 in the rural.

Anterior Segment Blindness:

Fifteen children were felt to have anterior segment acuity of less than 20/200 in one or both eyes. Approximately 50% of cases were secondary to trauma, measles, or vitamin A deficiency, with roughly equal representation of each. One-third had cataracts (four children), of which half (two) were congenital. There was one child with congenital and one with infectious corneal opacification, and one with congenital glaucoma. One-third of the blindnesses were bilateral.

While trauma was responsible for the majority of corneal scars, it was not an important cause of bilateral anterior segment blindness (Table 8). Only five such cases were found: one each of measles, vitamin A deficiency and congenital leukomata, and two with congenital cataracts. Vitamin A deficiency and measles therefore accounted for all the acquired bilateral anterior segment blindness in the small number of cases found. The prevalence of bilateral anterior segment blindness among these 1-6 year-olds was 5.3 per 10,000.

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TABLE 8

CAUSES OF BILATERAL ANTERIOR SEGMENT BLINDNESS

	Cases	Percent of Total
Measles	1	20
Hypovitaminosis A	1	20
Congenital Leukomata	1	20
Congenital Cataracts	2	40
	5	100%

Conjunctivitis:

Gross conjunctivitis was rampant; the vast majority purulent. In both the urban and rural samples 15.6% of the children were affected, 99.7% bilaterally. The highest prevalence was among the youngest age groups, 18% in 1-2½ year-olds. There was then a gradual decline to 13% in those 5½ years and older. There was no difference in prevalence by socio-economic status.

Serum Vitamin A Levels:

Blood was drawn on a total of 27 children with various pathologic lesions and an equal number of age and sex matched controls. These were divided into an earlier group of 14 and later group of 13 matched bloods. Because of the difficult terrain and delay in separating the serum the second group was grossly hemolyzed and the results inaccurate. The remaining 14 matched

bloods are a small sample, but the results suggest enough of a pattern to warrant discussion.

TABLE 9

PREVALENCE OF LOW SERUM VITAMIN A LEVELS AMONG ABNORMALS AND CONTROLS

Ocular Condition	Vitamin A less than 20ug/100ml positives / total
Bitot spots	2 / 2
Wrinkling with or without thickening	0 / 7
Bulbar Pigmentation	0 / 1
Old Corneal Lesion	1 / 4
Normal (age/sex/local matched controls)	2 / 14

Both children with bitot spots had serum vitamin A levels below 20 ug/100ml (17.8 and 2.6). They were 5 and 6-year-olds respectively, and their bitot spots bilateral. The levels in their matched controls were both over 20ug/100ml.

None of the eight children with conjunctival wrinkling, thickening, or bulbar pigmentation had a vitamin A level less than 20ug/100ml.

Of the four children with corneal disease, one had a serum level less than 20 ug/100ml (12.7). He was a 2 year-old with bilateral adherent leukomas recently treated for "measles" with corneal involvement at a local hospital. His matched control had a normal serum vitamin A level.

The other three cases of corneal scarring included a one-year-old with bilateral nebulae

thought to be secondary to infection, probably gonoccocal; a six-year-old with a staphyloma in one eye and phthisis in the other with onset at age two and presumed to be secondary to vitamin A deficiency; and a two-year-old with a unilateral adherent leukoma recently treated at the Bloom Hospital for vitamin A deficiency. The latter's vitamin A level was 33 ug/100ml.

Two of the 14 "controls" had vitamin A levels below 20 ug/100 ml. (16.6 and 19.1). Both were six-year-olds and without evident ocular pathology.

DISCUSSION

Vitamin A deficiency might well be the most important cause of acquired bilateral anterior segment blindness among the preschool-age population of El Salvador. Of the two cases of acquired bilateral blindness found, one was felt on clinical and historical grounds to be most compatible with healed keratomalacia. The other bilateral blindness was judged secondary to measles on the basis of a history of rash, the diagnosis allegedly assigned by the local hospital where he was treated. His chart was subsequently found at the Bloom Hospital in the course of the retrospective study, however, where it was noted he was transferred from the local hospital after nine days. On admission to Bloom he was diagnosed as having bilateral active keratomalacia, suggesting that this case too was secondary to hypovitaminosis A, exacerbated by the onset of measles[12].

The prevalence of vitamin A related corneal pathology was nonetheless far lower than anticipated and precluded its use in determining the effectiveness of the distribution program. There are roughly 45 new surviving cases and 15 new blindnesses per year in the entire country (excluding the controversial measles case*). While it might be argued the infrequency of bitot spots

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* Inclusion of this case would raise the estimated number of new annual surviving cases of corneal pathology and bilateral blindness to 60 and 30 respectively.

was the result of the first vitamin A distribution six months earlier, this would not explain the rarity of corneal scars.

Previous estimates, based on chemical surveys and hospital reviews, were considerably higher. While part of the discrepancy may be temporally related, the other studies preceding this one by 7-10 years, much is undoubtedly the result of differences in interpretation and technique. Chemical surveys can identify populations at risk of developing clinical disease, but they cannot predict the level of prevalence of such pathology. Extrapolation from hospitalized cases is hazardous without knowing the proportion of cases which come to the hospital and the size of the reference population. The present study, on the other hand, is an unbiased sample survey of the entire population of 1-6 year-olds in the country.

Although the numbers are small, all three cases of presumed vitamin A related corneal disease, and four out of five children with bitot spots, were rural. In contrast, almost all traumatic corneal scars were urban, where the prevalence was 19 times that of the rural areas. Trauma is frequently listed as a major cause of blindness in underdeveloped countries[4]. In El Salvador it accounts for the majority of acquired corneal scars among preschoolers, but little if any bilateral blindness.

Sixteen percent of children had gross conjunctivitis, but it too was not an important cause of bilateral blindness. Sixty percent (three of five cases) of bilateral anterior segment blindness were congenital.

The small number of clinical cases and vitamin A determinations support our impression that in El Salvador at least, excessive conjunctival wrinkling, thickening, and pigmentation are not reliable indicators of vitamin A deficiency.

STUDY II. HOSPITAL RECORD REVIEW

METHODS AND MATERIALS

The retrospective study was undertaken to provide epidemiologic insights into the nature of keratomalacia in El Salvador and provide an assessment of the effectiveness of the vitamin A distribution program.

Records were reviewed of all children ages 1-9 with selected discharge diagnoses from the Benjamin Bloom Childrens Hospital in San Salvador, the capital. This modern 360 bed institution is the premier facility in the country, with wide geographic coverage. It's Ophthalmology Department is especially interested in the problems of hypovitaminosis A, and a preliminary survey indicated record retrieval was excellent. In October of 1973 a separate ocular/protein-calorie malnutrition unit was established on the Eye Service. Referral to this unit is from the general Pediatric Service, where it has been the habit to consult with the Eye Department on these children when previously housed on the malnutrition wards. It was therefore felt that creation of the new unit did not impose an appreciable bias.

All primary and secondary discharge diagnoses are coded on ICD specific index cards[13]. A specially trained nurse consulted this index and retrieved all charts with primary or secondary diagnosis of:

260 - hypovitaminosis A

267 - protein malnutrition

268 - marasmus

269 - malnutrition - type unspecified

360 - conjunctivitis

371 - corneal opacity

378 - other ocular

379 - blindness

These were felt to include the vast majority of keratomalacia cases. While some additional cases might have been missed, it was impractical to review every discharge from the hospital.

After filling out identifying information, height, weight, and measles history, the nurse passed the chart and its form to the ophthalmologist, who reviewed the clinical history and determined the child's ocular status, and whether or not it was compatible with active keratomalacia or corneal xerosis with ulceration. A second, blind review for reproduceability indicated some shifting of specific clinical diagnosis, but rarely the classification of active vitamin A related disease. All charts with any significant ocular pathology were reviewed a third time by the ophthalmologist and the Principle Investigator, and a final concensus reached.

A three year period was studied, April 1971-March 1974. During the first however, the hospital was relocated, resulting in fluctuating numbers of beds and admission criteria, and the indexing changed, with a consequent loss of large numbers of charts. The results for 1971-72 are therefore included in the descriptive data, but omitted from any comparisons of pre-and post-distribution periods. These were limited to the years immediately preceding and following inaugeration of vitamin A distribution, April 1972-March 1973 and April 1973-March 1974 respectively.

RESULTS

The ICD files listed 3,713 charts with one or more of the selected diagnosis. Ninety-six percent (3,490) were retrieved. Approximately 280 charts mentioned some form of anterior segment abnormality.

Criteria for severe, active hypovitaminosis A related corneal disease ("positive cases") included the clinical description of corneal ulcer(s), keratomalacia, or active perforation ascribed to hypovitaminosis A by the attending pediatrician or ophthalmic consultant, the latter taking precedence, plus immediate treatment with massive doses of vitamin A.

Seventy-six cases met these criteria. In two additional instances, careful review failed to support the ophthalmologist's diagnosis of keratomalacia, and these omitted. Eighty-four percent of the 76 positive cases had been examined by a member of the Ophthalmology Department, almost half of these by Dr. Escapini, Professor and Head of Ophthalmology, and the Clinical Consultant to this study.

Number of Cases

There was no difference in the number of positive cases admitted in 1972-73 and 1973-74.

TABLE 10

ACTIVE CASES OF VITAMIN A RELATED CORNEAL DISEASE

	Number of Cases		
Clinical Description	1972-73	1973-74	Total
Keratomalacia	18	14	32
Corneal Ulcer	15	17	32
Total	33	31	64

Omitting those cases too young or too old to have received the distributed vitamin leaves the results unchanged.

TABLE 11

"ADJUSTED" CASES OF ACTIVE CORNEAL DISEASE

Clinical Description	Number of Cases 1972-73	1973-74	Total
Keratomalacia	8	7	15
Corneal ulcer	9	7	16
Total	17	14	31

Age

During the three year period, positive cases ranged in age from 2 months to 9 years. One-third of all cases were under one year, and half of these less than six months old. Almost two-thirds of all cases (58%) were less than 2, and 12% six or older. The age distribution during 1972-73 was identical to that of the following year. Even 1971-72, with its fewer cases, closely approximated these latter years.

TABLE 12

AGE DISTRIBUTION OF ACTIVE CASES OF VITAMIN A RELATED CORNEAL DISEASE

Age (years completed)	1971-72 Number[1]	Percent[2]	1972-73 Number	Percent	1973-74 Number	Percent
0	3	25	11	33	10	32
1	3	25	9	27	8	26
2	1	8	3	9	3	10
3	3	25	5	15	3	10
4	1	8	2	6	1	3
5	-	-	-	-	1	3
≥6	1	8	3	9	5	16
Total	12	99	33	99	31	100

1 Number of cases

2 Percent of annual total

The two clinical forms, corneal ulcer(s), and keratomalacia, had similar age distribution, the numbers declining with advancing years. Among ulcer patients, however, this decline was delayed by one year.

TABLE 13

AGE DISTRIBUTION OF ACTIVE CASES BY CLINICAL TYPE

APRIL 1971 - MARCH 1974

Age	Keratomalacia		Ulcer		Total	
(Years completed)	Number[1]	Percent[2]	Number	Percent	Number	Percent
0	13	35	11	28	24	32
1	7	19	13	33	20	26
2	3	8	4	10	7	9
3	5	14	6	15	11	14
4	3	8	1	3	4	5
5	-	-	1	3	1	1
≥ 6	6	16	3	8	9	12
Total	37	100	39	100	76	99

1 Number of cases

2 Percent of case specific total

Half of all the cases would have been ineligible for receipt of the vitamin during the biannual distribution immediately preceding onset of their corneal disease. Almost four-fifths of these were too young (less than a year of age). This limited the maximum potential effectiveness of the program to 50%.

TABLE 14

ELIGIBILITY OF CASES FOR RECEPIT OF VITAMIN A[1]

	Number	Percent of Total
Ineligible		
< 1 year old	28	37
> 5 years old	8	11
Total	36	48
Eligible		
Total (ages 1-4)	40	52
Total	76	100

(1) At the distribution that would have immediately preceeded the onset of their corneal disease.

Sex

Males comprised almost two-thirds of the 76 cases (62%), while females contributed two-thirds of the deaths (67%). The age distribution of male and female cases was identical.

Malnutrition

Clinically, 93% of the 3,490 admissions were severely malnourished (Grade III or worse). In contrast to corneal disease, the two sexes were equally represented. It was not possible, retrospectively, to divide these into kwashiorkor and marasmic types.

Every case of presumed vitamin A related corneal disease suffered severe, concomittant malnutrition. Since fluctuations in the number or age distribution of malnutrition admissions might conceivably influence the number of admissions with corneal disease, independent of the availability of vitamin A, the proportion of malnutrition admissions with concomittant corneal pathology (a malnutrition standardized rate) is probably a better index of the effect of the intervention program.

TABLE 15

ACTIVE CORNEAL DISEASE AMONG CHILDREN ADMITTED WITH SEVERE MALNUTRITION (1)

(BENJAMIN BLOOM CHILDRENS HOSPITAL)

Age (Years completed)	1972-73 Cases	1972-73 Rate/1000	1973-74 Cases	1973-74 Rate/1000
0	11	29	10	27
1	9	27	8	24
2	3	20	3	20
3	5	53	3	31
4	2	22	1	14
≥ 5	3	15	6	30
Total	33	26	31	25

(1) Includes only children of known age, 98% of the total.

Overall and age specific rates of vitamin A related corneal pathology among malnourished admissions were identical for the two years straddling the onset of distribution, 1972-73 and 1973-74 respectively. In each of the three years of study, the highest age specific rates of corneal pathology occurred in the fourth year of life.

Measles

All charts were reviewed for a history of recent measles (within one month of admission). When present, the family had invariably indicated it caused a marked worsening of the patient's condition, and assumed it was responsible for his acute decompensation and eventual admission.

During the only full, unbiased premeasles vaccination year, 1972-73, over twice as many

children with corneal involvement than without had given history of recent measles. A similar trend was apparent for each of the other two years. Because of the small number of cases, however, the difference is not statistically significant.

TABLE 16

MEASLES HISTORY AMONG CHILDREN ADMITTED WITH SEVERE MALNUTRITION

	1971-72		1972-73		1973-74		Total	
Measles History	A	B	A	B	A	B	A	B
Number	1	10	6	90	2	9	9	109
Percent of Admissions	8.3	1.4	18.2	7.3	6.5	0.7	11.8	3.4

A. With vitamin A related corneal disease

B. Without apparent vitamin A related corneal disease

The lowest age specific prevalence of recent measles history among preschoolers was during the first year of life: only one of 24 children with corneal involvement. The last case of measles, regardless of corneal involvement, was admitted in June of 1974, one month after completion of the measles vaccination campaign.

Seasonality

Measles, malnutrition, and vitamin A related corneal disease admissions are plotted in Figure 2. As already indicated, at least some of the change from 1971-72 is artifactual.

Where curves are constructed from small numbers of admissions, as in the present case of measles and corneal disease, they are apt to be erratic. These should be visually smoothed, with an emphasis on suggestive trends rather than absolute monthly peaks and dips.

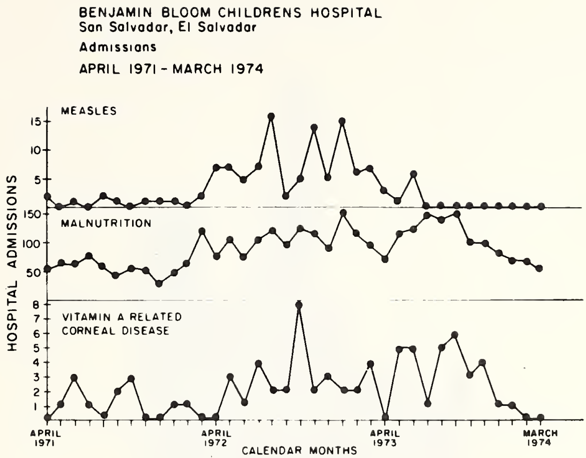

Fig. 2

In general, malnourished admissions, with and without corneal pathology, followed a similar course: from April-November 1972 both were biphasic; in December 1972 they began a slow upward climb and eventual plateau; beginning with January 1973 there was a slight dip to April of 1973, followed by a rise peaking in September 1973 and then an eventual decline. The corneal disease curve appears unaltered in the immediate postvitamin A distribution period. Adjustment for cases ineligible for participation on account of age did not alter the results.

Over the three year period, almost three-fourths (73%) of all vitamin A related corneal disease admissions occurred in the sixth month period extending from May through October.

In general, [illegible]

course, from [illegible]

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curve appears flattened in the [illegible]

ineligible for participation [illegible]

Over the three year period, [illegible]

admissions occurred in the [illegible]

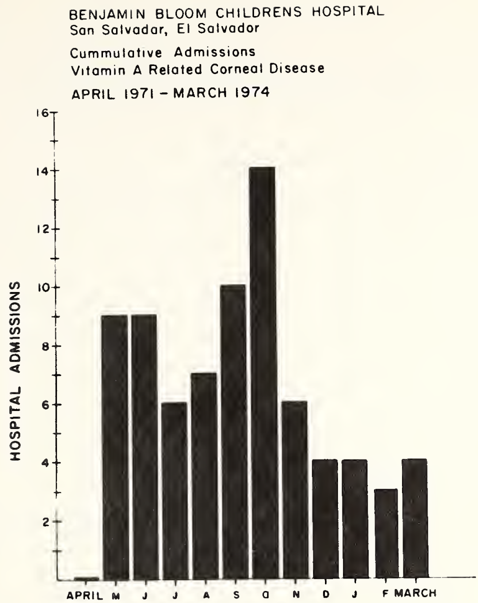

Fig. 3

Region

The country is divided into five regions. Bloom Childrens Hospital is located in San Salvador, the capital of both the Metropolitana region and the nation. One-third of all corneal cases came from here. Almost as many came from the adjoining Central and Paracentral regions. The fewest cases originated from the outlying Occidental and Oriental regions.

TABLE 17

REGION WHERE CORNEAL CASES ORIGINATED

Region	Number of Cases	Percent of Total	Rate per 100,000 pop.[1]
Metropolitana	24	32	27
Central	22	29	34
Paracentral	16	21	23
Oriental	8	11	6
Occidental	6	8	7

1 Denominator is estimated population, children aged 1-4[11].

DISCUSSION

Biannual countrywide distribution of massive doses of vitamin A had no effect on the number of children admitted with presumed vitamin A related corneal destruction, the proportion of malnourished patients with such destruction, or the age and seasonal distributions of these admissions. In fact, the seasonal peak occurred as usual, in the months immediately following the first distribution.

There are at least two explanations for this apparent lack of effectiveness: either the vitamin A capsules never reached the children at greatest risk, or the massive dose was inadequate prophylaxis.

No mass distribution program ever reaches 100% of the target population, even one as carefully

organized and vigorously pursued as El Salvador's. Measles serologic surveys before and after the initial campaign, which combined measles vaccination with vitamin A administration, demonstrate that at best, 80% of the children were reached[15]. Those missed are likely to have been the ones at greatest risk[16].

Because annual oral administration of 300,000 IU of vitamin A, or biannual administration of 200,000 IU results in an elevation of mean serum vitamin A levels and a reduction in the prevalence of xerosis conjunctivae and bitot spots, mild conjunctival evidence of clinical disease[17-20], it was assumed that mass distribution would prevent vitamin A related corneal destruction. As in the present study, however, corneal destruction is usually accompanied by severe generalized malnutrition[1,8,21-24], which interferes with both the absorption and utilization of vitamin A[25,26]. Since normally nourished children absorb only 50% of this massive dose[27], severely malnourished children might be expected to absorb even less. With their vitamin A stores even lower to begin with, this dose, massive as it is, may provide inadequate protection. At least two children presenting with uniocular keratomalacia went on to lose their second eye despite massive, daily, parenteral therapy with vitamin A.

We attempted to follow-up all positive cases of the 1973-74 season to determine whether any had actually received the vitamin during the preceding distribution. Unfortunately, more than half the cases had been too young to receive it, half of the remainder could not be located, and none of the rest had any objective evidence (vitamin A card) or knowledge of participation in the program.

The association between presumed vitamin A related corneal pathology and protein-calorie malnutrition is striking. Either they both arise from shared environmental deprivation, PCM exerts

its effect through decreased absorption and utilization of vitamin A when its availability is borderline, or corneal destruction is the direct effect of each, separately or in combination.

Vitamin A distribution was limited to 1-4 year-olds, the group commonly assumed to suffer from the disease. We were therefore surprised to find that a third of our cases were under one, and 12% six or older. Fully half of all cases would have been ineligible for receipt of the vitamin A capsule at the distribution immediately preceding the onset of their disease. The program was therefore limited to a maximum potential effectiveness of only 50% before it was even instituted. To overcome this limitation, distribution would have to be extended to neonates (in whom there is significant toxicity from the massive dose) and to school-age children (which might double the cost of the program).

The relationship between corneal destruction and the variables of sex and measles remains unclear. While males contributed two-thirds of the cases, mortality among female cases was four times as high, suggesting that only the sickest females were brought in, a bias in hospitalization rates which precludes any definitive statement about relative risks of disease in the community at large.

It is interesting (though not statistically significant) that malnourished children with presumed vitamin A related corneal disease had a higher rate of recent measles than malnourished children as a whole. Whether measles directly aggravates the potential for corneal destruction, or specifically interferes with vitamin A utilization is unclear.

Mass distribution of vitamin A capsules is not analogous to mass vaccination. During the first campaign, April-May 1973, measles vaccine and vitamin A were administered at the same time. Within one month measles had disappeared, while malnutrition admissions, with and without corneal

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involvement, followed its seasonal course. It is therefore unlikely that measles is an important predisposing factor to vitamin A related corneal disease in El Salvador, or that significant numbers of measles keratitis cases were misdiagnosed as vitamin A deficiency.

This study was a retrospective review of hospitalized cases, and may not accurately reflect the incidence or characteristics of vitamin A related corneal destruction in the population at large. The potential bias of hospitalized cases, presumably the sickest and most accessible children, is obvious. The charts were not designed for study and lack uniformity of data collection, standardization of observers, and serum vitamin A determinations (these are not performed in El Salvador). Nevertheless, few underdeveloped areas could support as reliable a study. The Bloom Childrens Hospital is a modern 365 bed facility with a well-trained staff interested in the problem of vitamin A related blindness, indexing is current and chart retrieval excellent, and it is nationally recognized as the premier facility in a relatively small, accessible country, as evidenced by the large geographic representation of the cases. In addition, the findings are consistent with those of the prevalence survey. The latter estimated 45 new surviving cases per year, or, with a generally accepted mortality of 50%, 90 cases annually. One of the three cases seen in the field had been treated at Bloom for an estimated 30 cases a year at that facility, essentially what was found. In addition, the prevalence survey's estimate that most cases of corneal disease had their onset before the age of 3 was confirmed.

STUDY III. COUNTRYWIDE BLINDNESS QUESTIONNAIRE SURVEY

METHOD AND MATERIALS

From July-September 1973 the Asociacion Demografica Salvadorena conducted a nationwide probability survey of 10,500 households in 330 clusters . They agreed to ask whether or not any

family member had great difficulty getting about in daylight because of poor visual acuity. There were no age restrictions.

A total of 44,223 individuals were included in the survey, of which 212 (0.48%) gave a history of blindness. The rate rose slowly from ages 0-1 (10 per 10,000) to ages 35-44 (32 per 10,000). From then on the rise was dramatic, with a blindness rate of 410 per 10,000 among those 65 and older. There was no significant sex differential. Blindness prevalence was identical for urban and rural dwellers, except among 2-4 year-olds, where the rural rate was almost three times the urban ($P < .05$).

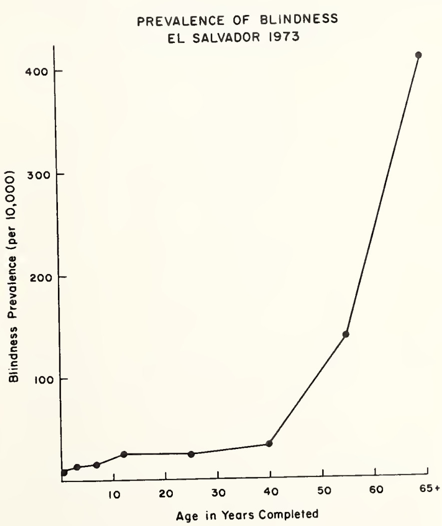

Fig. 4

DISCUSSION

Results of the blindness questionnaire are surprising in their conformity to expectations and findings of the prevalence examination survey, including a rural:urban preschool differential. No objective visual acuities were performed, and the eyes were not examined. While simplifying and speeding up the survey technique, this made it less objective. Yet the overall results and age regression approximate more objective results in similar populations[28]. Estimated blindness among 1-6 year-olds is roughly twice that of the examination prevalence survey, a nonstatistically significant difference. One would expect it to be at least this high. The definition was different, and the examination survey was limited to blindness caused by anterior segment disease, omitting retinal and neurologic etiologies. This suggests that a simple questionnaire, appropriately phrased, may give a remarkably accurate estimate of blindness prevalence.

CONCLUSIONS

The following pertains to El Salvador. We do not suggest identical conditions in other areas of the world.

1. Vitamin A deficiency is probably the leading, if not principle cause of acquired bilateral blindness among preschool-age children.
2. The magnitude of the problem, however, was considerably less than had previously been estimated from biochemical surveys and clinical impressions. Approximately 45 new surviving cases occur annually, roughly one-third resulting in bilateral blindness. The clinically oriented prevalence survey was the only unbiased means of acquiring such data.
3. The age structure of active hospitalized cases was such that half would have been ineligible for receipt of vitamin A at the distribution immediately preceding onset of their disease. The vast majority of these would have been less than a year old.
4. Distribution reached, at most, 80% of its target population (1-4 year-olds).
5. The maxiumum potential effectiveness of the program was therefore limited to 40% before distribution had even begun.
6. Mass distribution failed to influence the occurrence of the disease, even when adjusted for those it could not possibly have helped.
7. Three-fourths of all cases were hospitalized between May and October. The distribution had therefore been well-timed.
8. Severe, generalized malnutrition was a constant accompaniment of corneal destruction.
9. A recent history of measles was variably but consistently more common among children with vitamin A related corneal pathology than among malnourished admissions as a whole.
10. The dramatic reduction in measles cases following mass vaccination had little if any impact on the occurrence of active corneal disease.

IMPLICATIONS

1. Prevalence surveys of severe vitamin A related corneal disease are the only unbiased means of estimating the magnitude of vitamin A related blindness and the potential benefit of intervention. But they are expensive and time consuming, and rely heavily on the clinical judgement of the examiner.

2. Bitot spots are potentially more prevalent and clearly defined, requiring less examiner skill and a smaller sample. But it will not be a useful substitute for corneal pathology until its specificity as a marker for hypovitaminosis A, and its relationship to the eventual development of destructive corneal disease is determined.

3. We must learn more about the milieu in which corneal destruction exists, under differing conditions, in a rigorous, scientific manner. Of special concern is its relationship to age, sex, malnutrition, and other forms of acute and chronic insult (measles, sudden refeeding, parasite loads, etc.). Proper identification of predisposing factors is essential to the design of a successful intervention program.

4. Mass distribution is likely to be unrewarding. We now know the program in El Salvador was of sharply limited value before it was even launched. Subsequent distributions are likely to reach increasingly smaller proportions of the target population. Lack of concrete evidence that mass distribution can prevent vitamin A related corneal destruction is disturbing in light of the proliferation of such programs.

5. It is essential to determine whether vitamin A administration, oral or otherwise, can prevent corneal destruction in the face of severe, persistent malnutrition, and what doses and schedules, if any, are effective.

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APPENDIX #1

PROGRAM FOR THE DISTRIBUTION OF VITAMIN A IN EL SALVADOR

I. INTRODUCTION

The distribution of vitamin A capsules to all children aged one to five was planned over a two year time period with the deliveries being made at a rate of two per year. The capsules were initially distributed to an estimated 500,000 preschool children during the national vaccination campaign and was scheduled as follows:

First dosage - April 28 to May 20, 1973

Second dosage - November 17 to December 16, 1973

Third dosage - April 18 to July 31, 1974

Fourth dosage - November to December, 1974

The program was developed by Salvadorean personnel in collaboration with The American Foundation for Overseas Blind, New York, New York and The Center for Disease Control, Atlanta, Georgia. Below is an outline of the distribution program.

II. OBJECTIVES

1. To give four dosages of 200,000 I.U. vitamin A capsules at six month intervals to all children one year old and under five years.

2. To demonstrate the effectiveness of integrating a vitamin A distribution plan with a national vaccination campaign.

III. STRATEGY

A properly organized countrywide distribution plan requires extensive planning; motivated, well-trained personnel; participation of central, regional and local officials;

wide publicity and promotion. Careful supervision of the implementation phase and evaluations are additional requirements to ensure success. The following strategy was developed by the officials at The Ministry of Health and Social Assistance:

a) A Central Coordinating Committee at the central level was formed to provide the necessary procedural guides and to coordinate all the activities of the program, such as planning, implementation, promotion, supervision, and evaluation. The Committee defined the tasks and responsibilities of the Regional Directors.

b) A communication network between the central and regional levels was established. The Regional Directors were responsible for developing the area operational plans based on the outlines provided by the central level. They were also responsible for training their staff, volunteer personnel, field workers and participants from other Ministries in distributing the vitamin capsules.

c) Departmental and cantonal (local) teams were created to maximize efficiency and facilitate the operational plan. Every municipio in the country organized a team whose main function was to take a census, visit each village and distribute the vitamin capsules. The census information and weekly reports of activities were given to the Regional Directors.

d) Assistance was given by patrol soldiers in taking a census and registering children.

IV. PROCEDURES FOR PROGRAM EXECUTION

1. Promotion - An intense two month predistribution publicity campaign preceded each distribution period. Promotion was directed to all communities. This was performed by the Health personnel and by members of the Ministry of Defense, such as

"Comandantes Departmentales," "Comandantes Locales" and "Cantonales," and by members of the youth brigades and others. The promotional campaign was carried on through the press, radio, handbills, community meeting and notices in movie houses. The result was an aware, highly motivated public. Personnel responsible for promotion were:

a) The Ministry of Defense through the Territorial Service.

b) The Ministry of Public Health, through the Regional Department of Health.

c) A Departamental team formed by a representative of the "Comandante Departamental," by a Public Health Official and a Military nurse, coordinated by the Regional Director of Health or by the person by him designated to represent him.

d) A Municipal team formed by a representative of Public Health and the local "Comandante" leader, coordinated by the departamental representatives.

e) A Cantonal team formed by the Patrol Commander and by the Voluntary Health Collaborator, supervised by the corresponding municipal team members.

f) The Youth Brigade was used in San Salvador and Departamental capitals, coordinated in a central level.

2. Training - An integrated and coordinated program is feasible only when its staff is well-trained and carefully supervised. Three week training programs were designed and effected at the central, regional and local levels by their respective committees. The training topics included: goals and objectives of the program; program procedures and organization; the nature of vitamin A; purpose of vitamin A administration; specific job tasks and dosing technique; reporting and record keeping procedures; and community information and promotion.

3. Administration - A schedule of the distribution plan was formulated by the Central Coordinating Committee and forwarded to Regional and local Directors well in advance of the target distribution dates. The vitamin distribution was carried out by personnel at health mobile units at the time of the vaccination campaign. The regional directors were responsible for all logistics and for submitting accurate reports to The Central Coordinating Committee. In addition, the directors kept the committee advised on all program events and developments.

a) Reporting Procedure - The health services prepared monthly reports which were submitted to their respective regional office. Each mobile unit reported its information to their respective regional office on a weekly basis. Every regional office prepared monthly reports summarizing the local reports and forwarded them to the Central Coordinating Committee and to the office of the Regional Health Services. By following this procedure, The Central Coordinating Committee had monthly information on the status of the vitamin A distribution, as well as data on the other vaccination programs. This system was developed to diminish the pressure on the region of each service and each mobilization unit.

The vitamin capsules, registration cards, registration forms, report forms and vehicles were given to the regional levels from the central level.

b) Supervision - Designated staff at each level of operation was responsible for closely monitoring the campaign activities. The supervisory objective was to determine whether the distribution was in accord with established norms and procedures and to provide consultation as needed.

4. Registration - The field workers administering the vitamin capsules were carefully trained in the technique of its administration, as well as the registration procedures. They all received instructions for filling out forms and cards.

a) Every child who received a vitamin capsule was registered on a group registration form (census sheet).

b). Each child who received a vitamin A capsule was registered on a personal registration card which was given to the parent or guardian as a record of being dosed.

c) At subsequent distributions, the child's personal registration card was used to verify receipt of the vitamin. In order to keep accurate records, the dates of all vitamin dosages were recorded in designated boxes on the child's registration card. This is important in evaluating the effectiveness of vitamin A administration in preventing eye lesions due to its deficiency. The number of vitamin A dosages was not necessarily the same for each child.

5. Dosage - All field workers were carefully instructed in the procedure for dosing a child. The same procedure was followed throughout the country in all the distributing programs.

a) The snout of the capsule was cut and the contents of the capsule was squeezed into the child's mouth.

b) Only one capsule was given per child.

c) Only children one year old and under five were given the dosage.

d) Children with diarrhea were not given a dosage.

6. Evaluation - A quantitative and qualitative evaluation was designed and conducted by The Central Coordinating Committee. Anticipated and actual outcomes were compared. Staff performance evaluations were measured in an attempt to determine

level of efficiency, enthusiasm, accuracy and responsibility. Procedural obstacles and their solutions were noted. An assessment of xerophthalmia and mass distribution program was carried out under the auspices and direction of the American Foundation for Overseas Blind.

V. ORGANIZATION OF THE PROGRAM

The organization was the same as that of the Vaccination Campaign:

1. Central Level
2. Regional Level
3. Departmental Level
4. Local Level

1. At the Central Level, the Central Committee was composed of:

a) Dr. Julio Ernesto Astacio Minister of Public Health	Direction of the Program
b) Dr. Gerardo Mariona Baires General Director of Health	Collaborated in the direction of the program
c) Dr. Eduardo Navarro Rivas Oscar Nave Rebollo Roberto Pacheco A. Enrique Parado, and Delegates from the Ministry of Education, Public Works, State and Agriculture	Operations of the program
d) Ing. Alfredo Salomon A., Prof. Mario Raul Calderon	Supplies
e) Dr. Gerardo Mariona Baires Mayor Luis Alonso Amaya	Personnel

2. At the Regional Level, a committee was established similar to the Central Committee.

3. At the Departmental Level, it was of great importance to have an active and very dynamic committee which included all departmental authorities.

4. At the Local Level, a Committee was organized with the local authorities.

Translated from report by:

Dr. Eduardo Navarro Rivas
Ministry of Public Health
and Social Assistance

APPENDIX #2

SELECTION OF SAMPLING SITES

1. Primary Sampling Units: The entire country was divided into 228 units of roughly 10,000 houses each. For the most part, each unit was comprised of a single municipio, although smaller municipios were occasionally combined to produce the desired unit size. Fifty-nine primary sampling units were then selected from among these 228. Nineteen of the units were automatically selected because of their size and commercial and industrial importance. The remaining 40 units were selected on a purely random basis with equal probability.

2. Secondary Sampling Units: Each of the 59 primary sampling units was then divided into its constituent urban (head town) and rural (cantones) areas. These included a total of 35,000 houses. Each area was visited and the houses listed and mapped. The urban areas were divided into blocks of roughly 60 houses, and the rural areas into cantones, or parts of cantones of roughly 300 houses. Each town and canton within a primary unit was assigned a number from 1 upwards. The town was always assigned the number 1, and the cantones numbered from the closest to the furthest from the town. The number of houses to be sampled in each primary unit was proportional to the size of the unit, at the rate of 1 house for every 200 in the unit. Parts 1 and 2 were constructed by the Asociacion Demografica Salvadoreña for their special fecundity study. There were 334 secondary sampling units (parts of town and cantones) in the sampling frame.

3. Tertiary Sampling Units for the Vitamin A Project: Because of personnel limitations and time restraints in the present project, it was decided to sample only one secondary unit

within each of the 59 primary units, rather than all 334 secondary units. Accordingly a single secondary unit was chosen, randomly, from each primary unit, for a total of 59 sampling points. For the most part, individuals living in municipio head towns other than the three major areas of San Salvador, Santa Ana, and San Miguel are of the same socio-economic status as those living in the surrounding cantones. Thus, 56 of the 59 sites were chosen as indicated above and will be considered rural. The three urban sampling sites of San Salvador, Santa Ana, and San Miguel were limited to slum areas, rather than the random sample developed by the Asociacion Demografica Salvadoreña. In order to develop the required number of families (7,000) for the present study, a selection interval of one house in every 100 in the entire primary unit was used (twice the rate in the ADS sample). A total of 6,858 houses were therefore assigned. All of the houses for each primary unit were drawn from its single secondary unit. Additional secondary units were assigned in those instances where the randomly selected secondary unit appeared too small to provide the necessary number of houses, and were visited only after completion of the latter.

Date Due
